REMARKS

To advance prosecution, claims 1 and 22 are amended above to make explicit that which was implicit, and clearly explain that the present invention relates to information obtained from samples from a human patient who is asymptomatic for coronary artery disease, and that the information obtained by the claimed method is useful in helping one determine whether that individual has coronary artery disease. Support for the amendments to claims 1 and 22 is believed inherent in those claims as filed, but see also the specification at, for example, p. 1, lines 16-19; p. 11, lines 16-19; p. 15, lines 4-23; and p. 16, line 11, to p. 18, line 9.

In addition, to obviate part of the rejection under 35 USC § 112, second paragraph, the claims have been amended to recite that the cut points are "based on," rather than "related to," the corresponding factors specifically identified and recited by the claimed methods. Support for these amendment is implicit in the claims as filed, but see also the specification at, for example page 31, lines 10-26. .

It respectfully is submitted that the amendments presented above do not introduce new matter. Hence, entry and approval of the same, respectfully are solicited.

Claims 1-9, 11-13, 15-30, 32-34, and 36-42 were rejected under 35 USC § 101 as allegedly being drawn to non-statutory subject matter. (Paper No. 20070122.) For the reasons presented below, reconsideration and withdrawal of the rejection respectfully are solicited.

In making the rejection, the Examiner contended "[i]nsofar as claims 1 and 22 do not require 'patients,' Examiner interprets the verbiage in claims 1 and 22 as non-statutory 'abstract ideas' in accordance with MPEP § 2106." (*Id.*)

Initially, to undersigned counsel's (MacRae's) knowledge, no case has ever held that method/process claims must require the term "patients" in order to comply with § 101, and MPEP § 2106 certainly does not stand for that proposition. It therefore respectfully is requested that, should the Examiner maintain this rejection, the Examiner kindly provide a citation to some case, rule, or MPEP provision that requires the term "patients" to be a limitation in method/process claims in order to satisfy § 101.

In any event, with regard to the assertion that the claims recite "abstract ideas" because they do not require "patients," not only is that not the law, but it also appears that the Examiner has misinterpreted the present claims. The claims clearly are not so-called "abstract ideas," which refers to claims that merely recite "mathematical" equations. *See* MPEP § 2106(c) at 2100-10. Nor are they "method of treatment" claims, which would require the recitation of a patient or host. They simply, and clearly, are method/process claims that allow for an analysis of a sample obtained from a "human patient" (not a sample from just anywhere), by performing a series of well defined steps. And as is plainly apparent, the methods/processes claimed clearly recite several positive manipulative process steps (*e.g.*, "obtaining" and "assessing") that enable one to determine whether an individual has coronary artery disease or not.

Simply stated, the claims do not recite so-called "abstract ideas," the term "patients" is not required to be a limitation, and the claims are clearly directed to methods of analyzing patient samples to produce results that have real world value and, therefore, comply with § 101.[1/] That the methods/processes claimed do not require

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[1/] Even if, *arguendo*, the claims could somehow be construed as processes involving "abstract ideas," which clearly they cannot, processes that involve abstract ideas do not *per se* violate § 101. (*See* MPEP § 2106(c) ([m]ethods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be patentable.)

"patients" *per se* is irrelevant to § 101. The claims clearly and explicitly require positive manipulative steps involving a sample that has been obtained from a "human patient," and that the sample be manipulated in accordance with the methods/processes claimed to provide a very useful result. Thus, for these reasons alone, the rejection should be withdrawn.

In addition to the foregoing, as the MPEP explains in § 2107.01 (II), so long as the claimed invention is capable of performing some beneficial function, the utility requirement is satisfied:

> "***[t]o violate [35 U.S.C.] 101 the claimed [invention] must be totally incapable of achieving a useful result.***" *Brooktree Corp. v. Advanced Micro Devices, Inc.,* 977 F.2d 1555, 1571,24 USPQ 2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). *See also, E.I. du Pont De Nemours and CO. v. Berkley and Co.,* 620 F. 2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient . . ..The claimed invention must only be capable of performing some beneficial function ... An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . .A commercially successful product is not required . . .Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . .. In short, the defense of non-utility cannot be sustained without proof of total incapacity." If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. *See In re Brana,* 51 F.3d 1560, 34 USPQ2d 1435 (Fed. Cir. *1995); In re Gardner,* 475 F.2d 1389, 177 USPQ 396 (CCPA), reh'g denied, 480 F.2d 879 (CCPA 1973); *In re Marzocchi,* 439 F. 2d 220, 169 USPQ 367 (CCPA 1971). [Underline original, bold and italics added].

Here, the Examiner has not even contended, much less met his burden of demonstrating with factual evidence, that the claimed methods/processes are ***totally incapable of achieving any beneficial result whatsoever***, and the reason is clear – the specification is replete with unrebutted statements of the real world utility of the

methods claimed. (See, *e.g.*, the title of the present specification "DETECTION OF ASYMPTOMATIC CORONARY ARTERY DISEASE USING ATHEROGENIC PROTEINS AND ACUTE PHASE REACTANTS," and see also the specification at, for example, p. 1, lines 16 – 19 ("The present invention ...relates to improving the detection of coronary artery disease in patients who are asymptomatic and particularly for patients from the general population who are asymptomatic."); p. 11, lines 11 – 19; and p. 15, 21 – 23.) As is well settled, where, as here, the specification unquestionably contains statements explaining the real world utility of the methods claimed, and those statements have not been refuted with factual evidence, the utility requirement is satisfied. Bottom line: the methods claimed do, in fact, come squarely within and comply with 35 USC § 101.

This rejection under § 101 should be withdrawn.

Claims 1-9, 11-13, 15-30, 32-34, and 36-42 also were rejected under 35 USC § 101 for lack of utility because, according to the Examiner:

> Insofar as claims 1 and 22 do require "patients," claims 1 and 22 require, *inter alia*, patients having an "asymptomatic disease" (*i.e.* asymptomatic coronary artery disease). Claims 1 and 22 create a semantic construct wherein a person simultaneously has a disease, yet is asymptomatic for that disease. Applicant's specification asserts, *inter alia*, that methods incorporating "asymptomatic diseases" are useful for "discrimination between those who have coronary artery disease and those who do not" (see p. 15, lines 21-22).

The Examiner also asserted that:

> Applicant's specification does not disclose any semantic class of individuals who are simultaneously healthy and not healthy (*i.e.* individuals with asymptomatic disease), much less any clinical data involving any asymptomatic disease, much less a useful method based on such (non-existent) clinical data.

Initially, in response, it appears that the rejection is, at least in part, based on a misunderstanding of the phrase "asymptomatic disease" as used in the context of the present invention, and that misunderstanding precipitated the rejection. Generally speaking, an individual is asymptomatic for a particular disease when the individual either (1) does not have a particular disease state (*i.e.*, the individual is completely healthy with regard to a particular disease state), or (2) the individual has no overt manifestations of a particular disease state, but does have manifestations that are not plainly and readily recognizable or apparent without a relatively detailed analysis (*e.g.*, the individual is in a pre–disease state or has factors that are identifiable as the representing the disease state that are not readily apparent symptoms). Thus, an asymptomatic individual may be 100% healthy with regard to a particular disease state (and therefore is obviously also "asymptomatic" for that disease state), ***or*** may not be 100% "healthy" with regard to a particular disease state but is also not exhibiting readily apparent signs (symptoms) of that disease state.

Bottom line: there is nothing "semantic" about being "asymptomatic" for a particular disease state. The phrase is clear and understandable, and is one of two possibilities ("or") but ***not*** both ("and"). Indeed, a database search for the phrase "asymptomatic disease" revealed a similar understanding:

> **Asymptomatic**
>
> From Wikipedia, the free encyclopedia
>
> In medicine, a disease is **asymptomatic** while the patient does not experience symptoms. Asymptomatic diseases may not be discovered until the patient undergoes medical tests (X-rays or other investigations). Some diseases remain asymptomatic for a remarkably long time, including some forms of cancer.

> A patient's individual genetic makeup may delay or prevent the onset of symptoms.

In addition, a search of the USPTO's patent database for the phrase "asymptomatic disease" revealed that there are dozens of issued patents that employ that phrase. Some examples of the use of the phrase "asymptomatic disease" include:

> Thilly, US Patent No. 6,994,962, entitled "Methods of identifying point mutations in a genome," provides a similar definition of "asymptomatic diseases" as "[t]he arrays or DNA chips can be used as probes to detect harmful or deleterious alleles. ***For example, alleles which play a causal role in mortal disease (e.g., cancer) can be detected in individuals asymptomatic of the disease. An individual diagnosed in this manner could then begin appropriate prophylactic therapy.***"
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> Braun *et al.*, US Patent No. 6,821,739, entitled Methods of diagnosing Crohn's disease using Pseudomonas antigens," states that "[a]n individual can **[1]** have one or more symptoms of ulcerative colitis or Crohn's disease, or **[2]** can be asymptomatic or **[3]** disease free."
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> Moreno *et al.*, US Patent No. 6,816,743, entitled "Methods and apparatus for in vivo identification and characterization of vulnerable atherosclerotic plaques," states "[i]t has been generally observed that atherosclerosis, without associated thrombosis, is often an innocuous and asymptomatic disease."

Thus, the Examiner's assertion that claims 1 and 22 recite a "semantic construct wherein a person simultaneously has a disease, yet is asymptomatic for that disease," is simply wrong as a matter of fact. The claims do not. A person who is asymptomatic for a particular disease state is either healthy (and obviously asymptomatic) or simply does not have the readily apparent manifestations (symptoms) of the disease state (and is also therefore asymptomatic). But that does not make the claims a "semantic" construct.

In addition, the Examiner's criticism that "Applicant's specification does not disclose any semantic class of individuals who are simultaneously healthy and not

healthy (*i.e.*, individuals with asymptomatic disease)," also is not well founded. First, it seems that this argument, too, is based on a misunderstanding of the term "asymptomatic." Second, it is agreed that the present specification does not disclose any nonsensical "class of individuals who are simultaneously healthy and not healthy." But that, as explained above, is not what "asymptomatic" means. Again, asymptomatic means an individual is either healthy (and therefore not having readily apparent symptoms), ***or*** not healthy (but without having readily apparent symptoms). But it does not mean an individual is both healthy and not healthy as the Examiner contended.

The rejection is clearly based on a misunderstanding of the term "asymptomatic" and should be withdrawn.

Moreover, with further regard to the "clinical data" comment, to undersigned counsel's knowledge, no case has ever held that "clinical data" is required to satisfy the utility requirement for any claimed invention. Should the Examiner maintain this rejection, he is again requested to provide a citation to some case, rule, or MPEP provision that states that "clinical data" is required at all, much less to support claims directed to methods of analysis. Again, it is important to understand that the claims are ***not*** directed to *in vivo* clinical-type methods of treatment that require an *in vivo* result to be obtained. The claims do not require treating anyone with any medication for anything. So the Examiner's comment regarding so-called "clinical" data is not believed to be on point. The claims, simply stated, require a series of steps for analyzing a sample for atherogenic proteins and acute phase reactants, and the specification teaches that the claimed methods will yield important information that is useful in determining whether an asymptomatic individual does in fact have CAD.

More importantly, as discussed above, here again the Examiner has not given any legitimate ***factual basis*** for contesting the disclosed utility. Nothing the Examiner has contended provides any reason to even challenge, much less refute, the utility disclosed for the claimed methods. The present specification clearly and expressly discloses specific components that will identify particular elements that have been found to be present in CAD. That is a fact. And the specification clearly teaches specific methods to determine the absence or presence of those components.

Thus, for each of the foregoing reasons, there is nothing "inconsistent" with the disclosed utility when the claims are properly construed, and the rejection under 35 USC § 101 should be withdrawn.

Claims 1-9, 11-13, 15-30, 32-34, and 36-42 also were rejected under the utility requirement of the enablement provision of 35 USC § 112, first paragraph. In making the rejection the Examiner summarily contented:

> since the claimed invention is not supported by either a credibly asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. (*Id.*)

As discussed above, the rejections for lack of utility are wrong as a matter of fact and law. Thus, because the rejection under the utility requirement of the enablement provision of 35 USC § 112, first paragraph, is based solely on the arguments advanced with regard to the rejection under 35 USC § 101, and because those arguments are deficient as a matter of fact and law, this rejection, too, is equally improper for the same reasons discussed above and should also be withdrawn.

Hence, to avoid redundancy for the reasons discussed above, reconsideration and withdrawal of this rejection, too, respectfully are solicited.

Claims 1-9, 11-13, 15-30, 32-34 and 36-42 also were rejected under 35 USC § 112, second paragraph, as being indefinite. (Paper No. 20070122, p. 6.) For the reasons presented below, reconsideration and withdrawal of this rejection, also respectfully are solicited.

In making the rejection the Examiner contented that the phrase "related to..." was indefinite because, according to the Examiner, the identity of one or more standards for satisfaction of "related to" was purportedly not clear. In addition, the Examiner also asserted that:

> In preambles of claims 1 and 22 do not correspond to their respective method outcomes. For example, step (c) of claim 1 requires a step of performing "assessing" based on one or more comparisons. Whether/how mere "comparisons," absent baselines or reference values for comparison, amounts to an "assessment of the likelihood that a human patient who is asymptomatic for coronary artery disease has the disease" is not clear.
>
> In claim 22, step (d), the infinitives "to permit" and "to assess" are indefinite. Whether the act or process of "permitting" or "assessing" are completed or performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any, required for performing "permitting" or "assessing" is/are not clear.

As was settled almost 40 years ago in *In re Moore* 169 USPQ 236, 238 (CCPA 1971), all that § 112, second paragraph, requires is that the claims have a reasonable degree of precision and particularity – not absolute clear cut boundaries:

> set out and circumscribe a particular area ***with a reasonable degree of precision and particularity.*** It is here where the definiteness of the language employed must be analyzed - not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent are. (Emphasis added.)

Initially, in response, the claimed methods are to be construed as they would be by a person of skill in this art who has the present specification in hand ***and*** his or her

knowledge and experience in this particular field, not in the abstract. Although it is not seen, nor has the Examiner explained, why one of skill in this art would not understand that the claims require cut points, and that those cut points are "related to" a particular factor as recited, to advance prosecution, the claims have been amended to obviate that issue. As the Examiner will note, the claims now recite that the cut points are "based on" the particular factors recited in the claims. Hence, reconsideration and withdrawal of that basis of the rejection respectfully are solicited.

In addition, the claimed methods simply provide information that allows one of skill in this art to study and assess the information obtained as part of the claimed methods. And the claimed methods clearly and explicitly require cut points and an assessment of those cut points, or that a medical professional have the ability to assess those cut points. The cut points are, in turn, clearly and explicitly based on one or more of several expressly recited factors. There is nothing vague, unclear, or indefinite about that. And the specification clearly allows for the variability that a medical professional will always encounter in their practice.

Moreover, the specification clearly teaches the use of diagnostic curves based on an analysis of cut points as required by the claims. (See, *e.g.*, page 16, line 20, to page 19, line 25; and see also page 26, line 10, to page 32, line 19.) And the specification also clearly teaches how one of skill in this art can make an assessment of the information obtained by the claimed method. That is all that § 112, second paragraph, requires.

With regard to the Examiner's comments regarding the phrases "to permit" and "to assess" in claim 22, step (d), it is believed those terms are quite clear on their face

but, for clarification, they are not positive manipulative steps of the claimed method. They merely set forth the usefulness of the information obtained by practicing the claimed methods. Simply stated, "permitting" and "assessing" are neither recited nor required by claim 22.

Thus, for all of the foregoing reasons, reconsideration and withdrawal of each of the rejections, and allowance of all claims, respectfully are requested.

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(Date of Deposit)

C Londono
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